REMARKS

No amendments to the claims are made. Claims 1-28 were previously cancelled. Claims 29-40 are pending.

Written Description

Claims 35 and 39-40 are rejected under 35 U.S.C. § 112, first paragraph, written description. The Examiner states that while "the genus of heterologous regulatory sequences is adequately described because the mere name of the genus indicates a specific structure and function, that is not the case for the endogenous or homologous promoter that would be adjacent to the polynucleotide encoding SEQ ID NO:8" (Office Action, page 3).

Applicants respectfully traverse. Applicants point out that Claim 35 is directed to a recombinant DNA construct comprising the polynucleotide of Claim 29 operably linked to at least one **regulatory sequence**. Further, Claims 39 and 40 are directed to a plant comprising the recombinant DNA construct of Claim 35, and a seed comprising the recombinant DNA construct of Claim 35, respectively. Applicants submit that the subject matter of a recombinant DNA construct comprising the polynucleotide of Claim 29 operably linked to at least one regulatory sequence according to the claims has been described in the specification to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants note that the phrase "regulatory sequence" appears in the claims of many issued patents, such as, for example, claim 2 of US 6,319,710, and claim 1 of US 6,689,582, which was issued by the Examiner. While Applicants appreciate that each application is examined on its own merits, Applicants fail to see why a term that was once acceptable to the

Examiner (and other Examiners) in other applications is no longer acceptable to the Examiner in the present application. With respect to the instant application, the Applicants assert that the Examiner has improperly selected a narrow sub-genus or species of endogenous or homologous promoters from the claimed genus of at least one regulatory sequence, and rejected that sub-genus or species for lack or written description, where the claim is actually directed to the genus. The Federal Circuit has held that the written description requirement is "not [a] comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made." Amgen Inc. v. Tanskaryotic Therapies, Inc., 314 F.3d 1313, 1332 (Fed. Cir. 2003). Further, the Federal Circuit held that "under our precedent the patentee need only describe the invention as claimed, and need not describe an unclaimed method of making the claimed product." ibid., at 1333. In the Amgen case, the Federal Circuit upheld "the district court's reasoned conclusion that the specification's description of producing the claimed EPO in two species of vertebrate or mammalian cells adequately supports claims covering EPO made using the genus vertebrate or mammalian cells" ibid., at 1332. Similarly, Applicants assert that the written description requirement is met with respect to the claimed polynucleotide of Claim 29 operably linked to at least one regulatory sequence.

Further, Applicants note that "Satisfaction of this [written description] requirement is measured by the understanding of the ordinarily skilled artisan," Amgen Inc. v. Tanskaryotic Therapies, Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003). Applicants point out that regulatory sequences from *Hevea brasiliensis* are known in the art. For example, the HMg3 promoter from Hevea brasiliensis is described by Mee-Len Chye et al (Plant Molecular Biology, vol. 19, pages 473-484, 1992; cited on attached PTO Form 1449). Other known regulatory

elements from *Hevea brasiliensis* are reported by X. Deng (NCBI, "The 5' end promoter region of the rubber elongation factor" gi: 14211501, May 28, 2001) and by P. Arokiaraj et al (NCBI, "Isolation of putative regulatory sequence in the 5' upstream region of hevein (HEV1) of rubber tree (Hevea brasiliensis)" gi: 10304329, September 26, 2000).

In view of above discussion, Applicants submit that the written description requirements have been met. Claims 35, 39 and 40 encompass a recombinant DNA construct comprising the polynucleotide of Claim 29 operably linked to at least one regulatory sequence. The Examiner admits that the genus of at least one regulatory sequence is adequately described by the specification, at least with respect to heterologous promoters. With respect to non-heterologous regulatory sequences, the prior art describes several regulatory sequences from *Hevea brasiliensis*, as noted above. Applicants respectfully request withdrawal of the rejection.

Scope of Enablement

Claims 29-31 and 34-40 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement. With respect to Applicants' previous arguments in comparison of conserved active site regions between the sequence from *Zoogloea ramigera* (gi: 135759) and the claimed sequence, the Examiner states that:

> "The happenstance of residues being similar between two sequences does not define the sequences that govern the acetyltransferase activity of the protein. While information teaching experimentally identified active site residues (such as the Cys-X-Gly-X-Gly) is useful in making all the polynucleotides within the claimed scope, these few residues do not identify the breadth of as much as 85% identity and this motif is extremely common to enzymes across a broad array of substrates and catalytic activities. For these reasons, a single alignment does not teach the skilled artisan how to make the scope of the claimed invention, and the instant rejection is maintained." (Office Action, page 4).

Applicants respectfully traverse. The Federal Circuit has held that while the specification must comply with the requirements of 35 U.S.C 112, first paragraph, "[t]hat is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art. See Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997) ("[A] specification need not disclose what is well known in the art.")" AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir., 2003).

Applicants refer to Appendix B for a comparison of the claimed sequence with the sequence from *Zoogloea ramigera* (gi: 135759) disclosed by Palmer et al (J. Biol. Chem., 1991, 266: 8369-8375), as well as *Raphanus sativus* (gi: 1542940) and *Saccaromyces cerevisiae* (gi: 311088). Amino acids conserved among all the sequences are indicated with an asterix above the conserved residues. SEQ ID NO: 8 shares 73.2% sequence identity with the *R. sativus* sequence, 50% with the *S. cerevisiae* sequence, and 38.3% with the *Z. ramigera* sequence. See Vollack et al ("Cloning of a cDNA Encoding Cytosolic Acetoacetyl-Coenzyme A Thiolase from Radish by Functional Expression in *Saccharomyces cerevisiae*" Plant Physiol., 1996, vol. 111, pages 1097-1107). This comparison demonstrates that the sequences share the conserved active site region, in particular the two active site cysteine residues. One skilled in the art would appreciate that the more highly conserved a residue is, the less likely that it could be modified and function maintained.

In addition to the sequence alignment data in Appendix B, Vollack presents successful complementation of an acetyl-CoA acetyltransferase deficient *S. cerevisiae* with the acetyl-CoA acetyltransferase from radish (*R. sativus*). The two sequences share 51.8% identity. The complemenation studies demonstrate to one of ordinary skill in the art a possible manner in which to test for functional activity in sequences with the claimed identity. From the examples set forth in Palmer et al, Vollack et al, and the attached alignment (Appendix B), one skilled in the art could quickly determine which amino acid residues might be modified in SEQ ID NO:8 without a likely change in function, and further verify which changes in sequence identity affect function through complementation studies. Therefore, applicants assert that the entire scope of the claims is enabled.

CONCLUSION

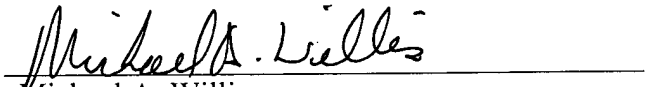
Applicants thank the Examiner for the statement that the claimed subject matter is considered free of the prior art, and note that claims 32 and 33 are not rejected. Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2119-4268. A DUPLICATE OF THIS SHEET IS ATTACHED.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2119-4268. A DUPLICATE OF THIS SHEET IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: February 18, 2005 By: 

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APPENDIX B

Comparison of the amino acid sequences of the Acetyl-CoA acetyltransferases from *Hevea brasiliensis* clone with SID NO: ehb2c.pk006.05 (SEQ ID NO:8), Raphanus sativus set forth in NCBI General Identifier No.:1542940, Saccaromyces cerevisiae set forth in NCBI General Identifier No.:311088, and *Zoogloea ramigera* set forth in NCBI General Identifier No.:135759. Amino acids conserved among all sequences are indicated with an asterix above the conserved residues. Dashes are used by the program to maximize alignment of the sequences. Residues found to be conserved in all thiolase sequences including the active site residues cysteine (▲) are underlined (Palmer et al. 1991, J. Biol.Chem. 266: 8369-8375 and Vollack et al. 1996, Plant Physiol. 111:1097-1107).

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                *                   ***  * * *      *  **       *
SEQ ID NO:8     MSPSSDSIN-PRDVCIVGVARTPMGGFLGSLSSFSATKLGSIAIQAALKR--ANVDPSLV
Gi:1542940      MAHSADSSDNPRDVCIVGVARTPMGGFLGSLSSLPATKLGSLAITAALKR--EMLTRLWS
Gi:311088       MSQ---------NVYIVSTARTPIGSFQGSLSSKTAVELGAVALKGALAKVPELDASKDF
Gi:135759       MSTPS---------IVIASARTAVGSFNGAFANTPAHELGATVISAVLERAG-VAAGEV

                 *   * ** *  ** **** *  **          *  * *   *  *    *  *
SEQ ID NO:8     QEVFFGNVLSANLGQAPARQAALGAGIPNSVICTTINKVCASGMKATMLAALTIQVGIND
Gi:1542940      KEVVFGNVLSANLGQAPARQAALGAGISNSVICTTVNKVCASGMKAVMIAAQSIQLGIND
Gi:311088       DEIIFGNVLSANLGQAPARQVALAAGLSNHIVASTVNKVCASAMKAIILGAQSIKCGNAD
Gi:135759       NEVILGQVLPAGEGQNPARQAAMKAGVPQEATAWGMNQLCGSGLRAVALGMQQIATGDAS
                                                      ▲
                  **** ***   *        *   *     *    *** *      **  **  *
SEQ ID NO:8     IVVAGGMESMSNAPKYLAEARRGSRLGHDTIIDGMLKDGLWDVYNDFGMGVCAEICADQH
Gi:1542940      VVVAGGMESMSNTPKYLAEARKGSRFGHDSLVDGMLKDGLWDVYNDCGMGSCAELCAEKF
Gi:311088       VVVAGGCESMTNAPYYMPAARAGAKFGQTVLVDGVERDGLNDAYDGLAMGVHAEKCARDW
Gi:135759       IIVAGGMESMSMAPHC-AHLAGGVKMGDFKMIDTMIKDGLTDAFYGYHMGTTAENVAKQW

                   *   *  *  *       *  * *  ****    *  *     *  **
SEQ ID NO:8     NITREEKDSYAIRSFERGNSAQNGGVFSWEIVPVEVSGGRGKSVMVVDKDEGLIKFDA-A
Gi:1542940      EITREQQDDYAVQSFERGIAAQESGAFTWEIVPVEVSGGRGRPSTIVDKDEGLGKFDA-A
Gi:311088       DITREQQDNFAIESYQKSQKSQKEGKFDNEIVPVTIKGFRGKPDTQVTKDEEPARLHV-E
Gi:135759       QLSRDEQDAFAVASQNKAEAAQKDGRFKDEIVPFIVKGRKG-DITVDADEYIRHGATLD

                     *       * *** ***   *****  * *                      *
SEQ ID NO:8     KLRKLRPISRI--GSVTAGNASIISDGAAALVLVSGEKAIELGLQVIARIRGYGDAAQAP
Gi:1542940      KLRKLRPSFKENGGTVTAGNASSISDGAAAIVLVSGEKALQLGLQVLAKVKGYGDAAQEP
Gi:311088       KLRSARTVFQKENGTVTAANASPINDGAAAVILVSEKVLKEKNLKPLAIIKGWGEAAHQP
Gi:135759       SMAKLRPAFDKE-GTVTAGNASGLNDGAAAALLMSEAEASRRGIQPLGRIVSWATVGVDP

                      *  *  **             *  * ****        * *   *   *  ***
SEQ ID NO:8     ELFTTAPALAIPKAISNAGL--EASQIDYYEINEAFSVVALANQKILGLNPEKLNVHGGA
Gi:1542940      EFFTTAPALAIPKAIAPNSPYSESYQVDYYEINEAFAVVALANQKLLGISPEKVNVNGGA
Gi:311088       ADFTWAPSLAVPKALKHAGI-EDINSVDYFEFNEAFSVVGLVNTKILKLDPSKVNVYGGA
Gi:135759       KVMGTGPIPASRKALERAGW-KIGDLDLVEANEAFAAQACAVN-KDLGWDPSIVNVNGGA
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                  *** * ****   ***          *    * ***       *
SEQ ID NO:8       VSLGHPLGCSGARILVTLLGVLRHKNGKYGVASICNGGGGASALVLELMSVGRVGRSLL
Gi:1542940        VSLGHPLGCSGARILITLLGILKKRNGKYGVGGVCNGGGGASALVLEVV----------
Gi:311088         VALGHPLGCSGARVVVTLLSILQQEGGKIGVAAICNGGGGASSIVIEKI----------
Gi:135759         IAIGHPIGASGARILNTLLFEMKRRGARKGLATLCIGGGMGVAMCIES----------L
                                                  ▲
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